COLORADO STATE BOARD OF PHARMACY January 17, 2008

Minutes

The Colorado State Board of Pharmacy meeting was convened by President E. Katherine Edelblut, RPh, at approximately 8:40 a.m. on Thursday, January 17, 2008 at 1560 Broadway, Conference Room 1380 A & B, Denver, CO. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Jeannine G. Dickerhofe, RPh, Rich Doyle, RPh, E. Katherine Edelblut, RPh; Paul Limberis, RPh; and Averil Strand, RN.

Staff members attending were Wendy Anderson, Program Director; Chief Inspector, Chris Gassen; Inspectors Billie Marseilles, RPh; Susan Martin, RPh; and Mark O'Neill; Tia Johnson, Licensing and Complaint Specialist, and Aaron Acker, Specialist, Office of Expedited Settlement. Also present were Jo Kaye, Assistant Attorney General, and Jack Wesoky, Assistant Attorney General, to advise the Board.

APPROVAL OF MINUTES

The Board approved and accepted the minutes from the November 15, 2007 meeting as amended, and the minutes from the December 14, 2007 meeting as amended.

ADDITIONS TO THE AGENDA

Ms. Anderson advised the Board of the following additions to the agenda:

- Case #2008-1638 regarding Dan M. Valentine, RPH 12002
- Case #2008-1734 regarding Tamara L. Reynolds, RPH 14951
- Case #2008-1978 regarding JOM Pharmaceuticals, Out of State Wholesaler applicant
- Inspector's Report regarding Star Drug, Inc., PDO 125-3

APPEARANCES

Lane J. Brunner, Ph.D., Dean, School of Pharmacy, Regis University, handed out information and provided an update on the Regis University School of Pharmacy.

HEARINGS

The Board conducted a public hearing concerning additions or amendments to the following regulations: 3.01.20, 3.02.00, 10.00.00, and 21.00.00 (3 CCR, 719-1) The hearing began at 9:40 a.m. and was held in Conference room 1380 AB at 1560 Broadway, Denver, Colorado. The Board discussed all proposed changes to the rules then adopted rule 3.01.20 and rule 10.00.00 as submitted. The Board tabled further action concerning rule 3.02.00 and 21.00.00, pending further review.

REPORTS

President's Remarks

None.

Program Director's Report

Ms. Anderson explained to the Board members that new Department of Regulatory Agency (DORA) calendars were contained in their folders. She explained DORA's new logo as well as its mission statement. In addition, she told the members that a document entitled, "Changes in Healthcare Professions' Scope of Practice: Legislative Considerations" was also in their folders. This was provided by Division Director Rose McCool with a cover letter.

Ms. Anderson requested and the Board approved the noticing of its public meetings on the internet and in the Division's reception area. Ms. Anderson requested that the Board disregard a revision to Board rule 2.01.10 which was in the agenda packet. Staff will make additional revisions and bring back at a future meeting. The Board then considered rule 4.02.00 and a request from staff inquiring how long examination scores would be considered valid. The Board decided that examination scores would be valid for 24-months. Staff agreed to propose amendments to the rule for Board review. The Board then considered revisions to rule 5.01.31. After due consideration, the Board moved these revisions to hearing. The Board then considered revisions to rule 15.00.00, Wholesalers. After due consideration, the Board moved these revisions to hearing. The Board reviewed and moved to hearing proposed rule 22.00.00, Initial Decisions.

Ms. Anderson then requested the Board decide whether it would accept examination scores from an examination other than the NAPLEX from the states of Florida or California for the purposes of license transfer. Both of these states now utilize the NAPLEX, but have not always done so. After due consideration, the Board decided that it would accept license transfer applicants from Florida or California who took that state's licensing examination at the time of original licensure. In addition, the Board decided that a pharmacist could transfer their license from another state as long as that license was in good standing. That state did not have to be the state where the pharmacist was originally licensed by examination.

The Board then selected Jeannine Dickerhofe to be its voting delegate at the NABP Annual Conference to be held in Baltimore, Maryland from May 17-20, 2008. Rich Doyle agreed to be the alternate.

Ms. Anderson then requested and was provided issues the Board wanted to discuss at its February planning meeting. Ms. Anderson then passed on an invitation from Nancy Stolpman, the Director of Pharmacy at the University of Colorado Hospital, for the Board to visit the pharmacy to see its new CytoCare machine. Board directed staff to set a time at an upcoming meeting.

Finally, Ms. Anderson updated the Board on the implementation of the Electronic Prescription Drug Monitoring Program. A "go live" date has not yet been established, but envision in the next couple weeks.

Colorado Pharmacists Society (CPS) - Rich Doyle, RPh

Val Kalnins reported that the next CE program is the 16th Annual Winter CE Seminar to be held January 20-23, 2008 at the Sheraton Steamboat Springs. Fifteen hours of CE will be provided. Planning has begun for the 2008 CPS Annual Summer Meeting at

the Copper Mountain Conference Center from June 13-15, 2008. Ten hours of ACPE approved education will be provided

CPS participated in the first Pharmacist Line 9. Seven pharmacists volunteered for this event in which the public is invited to call 9 News to speak to a pharmacist. They received over 175 calls between the hours of 5:30 -7:30 AM. The questions ranged from how to treat cold symptoms to what needs to be done to switch plans under Medicare Part D. The management of 9 News was pleased with the response and has agreed to make Pharmacist Line 9 a regular feature every other month. The next event is scheduled for February 12 from 4:00-6:30 p.m.

The Colorado Pharmacists Society is once again a partner of the 9 Health Fair from April 12-20, 2008 and is helping the Fair organizers get pharmacist volunteers for designated sites throughout Colorado. CPS will post on its website how to sign up as a volunteer and a list of sites requesting pharmacists. To assist pharmacists and pharmacy students in providing services at fairs, tools have been developed and will be posted on the website. These tools include pdf files that can be downloaded, printed and distributed as handouts by the volunteers to increase their level of comfort in discussing issues from asthma, to weight management and smoking cessation.

Governor's Expert Emergency Epidemic Response Committee (GEERC) - Paul Limberis, RPh

The GEEERC met on January 8, 2008. Paul Limberis and Jeannine Dickerhofe represented the Colorado State Board of Pharmacy. The First Responder Definition Policy was updated to include fire fighters, county coroners, and the National Guard. The 2007 POD Squad Mass Vaccination Full-Scale Statewide Exercise occurred November 15-17, 2007. Over 12,000 members of the general public were vaccinated with influenza vaccine on November 17, 2007. Systems were tested. Strengths as well as opportunities for improvement were identified. A report on the Colorado Regional health Information Interoperability Organization was made. This report involves a sharing of information among health providers. An update on biosurveillance plans for the upcoming Democratic National Convention was discussed.

Intern & School Relations -Jeannine Dickerhofe, RPh

Cathy Jarvis from the University of Colorado Health Sciences Center School of Pharmacy gave the report. She reported that by the following week, all pharmacy students would be at the Anschutz campus. She inquired if the Board was still interested in having a board meeting at the pharmacy school and if the Board was interested in taking a tour of the school's new facility. The Board directed staff to pursue both opportunities. Dr. Jarvis told the Board that the number of applications to the school has been declining. She explained that the school just recently began requiring the PCAT (Pharmacy College Admission Test) as an admission requirement and felt that the number of applicants had declined because the PCAT was now required.

Val Kalnins reported that the 2008 Legislative Session has a major focus on health care – 82 bills affecting health care have been introduced in the House and 35 in the Senate.

Three bills affecting pharmacy have been the focus of pharmacy organizations in Colorado.

- HB 1062 Expansion of HB 1021
- HB 1032 Change in payments to pharmacies
- Mail Order Bill Allow Medicaid patients to receive Rxs through the mail

HB 1062 expands the Prescription Drug Information and Technical Assistance Program to include persons receiving drug benefits from any program administered by the department of health care policy and financing.

HB 1032 directs Department of Health Care Policy and Financing to review the impact and calculate the anticipated reduction in the reimbursement rate to be paid to pharmacies due to the federal Deficit Reduction Act. The department then should adjust the Medicaid pharmacy dispensing fee for generic drugs to ensure that those fees cover the cost of dispensing.

Mail Order Bill allows a Medicaid recipient to use a mail order pharmacy for maintenance prescription drugs. It prohibits the mail order pharmacy from charging the recipient more than the Medicaid copayment.

Rules - Rich Doyle

None

Inspectors

Request from Walgreen Co.

The Board considered a memorandum from Mark R. O'Neill regarding a request from Walgreen Co. to electronically store non-controlled substance and schedule III through V controlled substance prescription orders. After due deliberation, the Board tabled further action concerning this request pending additional review.

Star Drug, Inc., PDO 125-3

At its meeting on January 17, 2008, the Colorado State Board of Pharmacy considered a memorandum from Chris Gassen and an Inspection Report from Mark O'Neill detailing an inspection of Star Drug on 9/5/07, which demonstrated the pharmacy's deficiencies in conforming with Rules 3.01.22, 3.01.23, and 3.01.24 concerning labeling of automatic cassettes.

After due consideration, the Board voted to initiate complaints against Star Drug, Inc. and its pharmacist manager, Thomas Bratz, RPh.

OLD BUSINESS

Stipulations and Final Agency Orders

Dennis H. Blair, RPh 11820

The Board considered correspondence from Mr. Blair requesting release from the terms of his Stipulation and Final Agency Order. The Board also considered a report from Tia Johnson, Licensing and Complaint Specialist, discussing Mr. Blair's compliance. After due consideration, the Board voted to release Mr. Blair from the terms of his Stipulation and Final Agency Order.

James F. Zugelder, RPh 15789

The Board considered correspondence from Mr. Zugelder requesting release from the terms of his Stipulation and Final Agency Order. The Board also considered a report from Tia Johnson, Licensing and Complaint Specialist, discussing Mr. Zugelder's compliance. After due consideration, the Board voted to release Mr. Zugelder from the terms of his Stipulation and Final Agency Order.

NEW BUSINESS

Pharmacist Renewal Issues

Thomas H. Brady, RPh 11381

The Board reviewed an Agenda Memorandum from Tia Johnson, concerning Mr. Brady's affirmative answer to question #2 on his pharmacist renewal application.

After due consideration, the Board voted to initiate a complaint against Mr. Brady's pharmacist license.

Eldon D. Edge, RPh 16320

The Board reviewed an Agenda Memorandum from Tia Johnson, concerning Mr. Edge's affirmative answer to question #4 on his pharmacist renewal application.

After due consideration, the Board accepted Mr. Edge's explanation concerning the affirmative answer, and determined no further action was necessary.

Jacquelyn Goldberg, RPh 14903

The Board reviewed an Agenda Memorandum from Tia Johnson, concerning Ms. Goldberg's affirmative answer to question #4 on her pharmacist renewal application.

After due consideration, the Board accepted Ms. Goldberg's explanation concerning the affirmative answer, and determined no further action was necessary.

Edward F. Reynolds, RPh 15664

The Board reviewed an Agenda Memorandum from Tia Johnson, concerning Mr. Reynolds' affirmative answer to question #2 on his pharmacist renewal application.

After due consideration, the Board accepted Mr. Reynolds' explanation concerning the affirmative answer, and determined no further action was necessary.

Complaints

Contract Pharmacy Services, PDO 24-124

2008-1454

Paul Limberis, R.Ph., recused.

After due consideration of the available information, the Board voted to refer the case for discipline.

The Board also directed staff to refer information contained in this case to the Colorado and New Jersey Board of Medical Examiners.

Caron A. Herre, RPh 14940

2008-1455

Paul Limberis, R.Ph., recused.

After due consideration of the available information, the Board voted to refer the case for discipline.

William H. Loftin, Jr., RPh 9715

2008-1456

Paul Limberis, R.Ph., recused.

After due consideration of the available information, the Board voted to refer the case for discipline.

Carrie D. Clawson, RPh 15565

2008-1559

Jeannine Dickerhofe, RPh, recused.

After due consideration of the available information, the Board voted to dismiss the complaint.

Robert J. Doherty, RPh 16511

2008-1449

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Lorraine M. Fling, RPh 14799

2008-1179

After due consideration of the available information, the Board voted to dismiss the complaint.

Ft. Lewis College Student Health Center, OO 259

2008-1332

After due consideration of the available information, the Board voted to dismiss the complaint.

Yoseph G. Mekonnen, RPh 14789

2008-1007

Jeannine Dickerhofe, RPh, recused.

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Jose A. Monreal, RPh 15278

2008-1323

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After due consideration of the available information, the Board voted to dismiss the complaint.

David S. Ornes, RPh 12550

2008-08607

Paul Limberis, RPh, recused.

After due consideration of the available information, the Board voted to refer the case for discipline.

Byron J. Padilla, RPh 16516

2008-1473

After due consideration of the available information, the Board voted to refer the case for discipline.

People's Drug Store, PDO 3-2

2008-1095

After due consideration of the available information, the Board voted to refer the case for discipline.

George H. Tracey, RPh 7901

2008-1096

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Redwood Unit Dose, Inc., Unregistered

2008-1008

After due consideration of the available information, the Board voted to issue a Cease and Desist Order against the unregistered practice of Redwood Unit Dose, Inc.

Joel P. Schulte, RPh 17530

2008-1128

After due consideration of the available information, the Board voted to dismiss the complaint.

Oliver W. Stanford, RPh 14507

2008-1390

Jeannine Dickerhofe, RPh, recused.

After due consideration of the available information, the Board voted to dismiss the complaint.

After due consideration, the Board also voted to initiate complaints against Cornell Prescription Pharmacy and its pharmacist manager, Thomas A. Lotocki, RPh.

Target Pharmacy T-2021, PDO 627

2008-1560

After due consideration of the available information, the Board voted to refer the case for discipline.

USDrugs.com, OSP 5674

2008-1614

After due consideration of the available information, the Board voted to dismiss the complaint.

Robert J. Valuck, RPh 12376

2008-0859

After due consideration of the available information, the Board voted to dismiss the complaint.

Walgreen Pharmacy #09561, PDO 637

2008-1180

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After due consideration of the available information, the Board voted to refer the case for discipline.

Walgreen Pharmacy #2857, PDO 7-45

2008-1563

After due consideration of the available information, the Board voted to refer the case for discipline.

WellDyneRx, PDO 37-50

2008-1099

After due consideration of the available information, the Board voted to dismiss the complaint.

Terry L. Kurtz, RPh 15703

2008-1100

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Dan M. Valentine, RPh 12002

2008-1638

After due consideration of the available information, the Board voted to refer the case for discipline.

Tamara L. Reynolds, RPh 14951

2008-1734

After due consideration of the available information, the Board voted to refer the case for discipline.

JOM Pharmaceuticals, Out of State Wholesaler applicant 2008-1978

After due consideration of the available information, the Board voted to issue an Outof-State Wholesaler registration to JOM Pharmaceuticals and to dismiss the complaint.

LICENSING

Other Outlets, New

The Board approved the registration of 1 new outlet.

Prescription Drug Outlets, New (In-State)

The Board approved the registrations of 5 new in-state outlets.

Prescription Drug Outlets, New (Out-of-State)

The Board approved the registrations of 12 new out-of-state outlets.

Wholesalers

The Board approved the registrations of 22 Out-of-State Wholesalers.

The Board did not approve any In-State Wholesaler registrations.

Manufacturers

The Board did not approve any Manufacturer registrations.

Limited Licenses

The Board did not approve any Limited License registrations.

Licensure by Examination

The Board ratified the licensure of 15 applicants for licensure by examination.

Licensure by License Transfer

The Board ratified the licensure of 19 applicants seeking licensure through license transfer. It was noted that these licensees met all of the requirements for licensing under the provisions of section 12-22-116, C.R.S.

Licensure Issues

Non-Resident Wholesaler Licensure Issues

DIT Healthcare Distribution, Inc.

After due consideration of the available information, the Board tabled further review of this application, pending receipt of additional information.

Non-Resident Prescription Drug Outlet Licensure Issues

Boudreaux's Specialty Compounding

After due consideration of the available information, the Board denied its application for a non-resident prescription drug outlet registration.

Pharmacist Licensure Issues

Oren J. Oubre

After due consideration of the available information, the Board directed the issuance of pharmacist license to Mr. Oubre.

Pharmacist Intern Licensure Issues

Orlando R. Garcia

After due consideration of the available information, the Board denied the pharmacist intern licensure application.

MISCELLANEOUS

Correspondence, etc.

Request from Deborah A. Wells

Ms. Wells' questions, followed by the Board's corresponding responses, are detailed below.

1. If a patient has a prescription for a non-controlled substance that is a medication for chronic illness such as diabetes or hypertension, written as a 30

day supply with 11 refills, would it be acceptable in your state for a pharmacist, at the request of, or with the consent of the patient, to fill it for a 90 day supply and adjust the number of remaining refills? In that situation, would it be acceptable/legal for the pharmacist to use professional discretion to dispense the 90 day supply of a maintenance drug without consulting the physician?

In both instances, dispensing pharmacists are allowed to use their professional judgment based on each specific situation at hand. Regulation 3.00.20 states, among other things, that no licensee shall dispense any drug to any person in such quantity or in any situation where the licensee knows or reasonably should know said drug has no recognized medical utility or application.

2. If the prescription is written to be refilled PRN, or as needed, is that legitimate in Colorado? Would it need to say what number to dispense, and could the pharmacist dispense a 90-day rather than a 30-day supply without consulting the physician?

While a prescribing practitioner may state "PRN" or "as needed" on a prescription order to reflect the number of refills that may be dispensed, a specific quantity to be dispensed shall be stated on each prescription order.

3. Are mail order pharmacies based in Colorado subject to the same requirements as retail pharmacies, when considering the questions above?

Yes.

Proposal from Thomas Branigan, RPH, Regarding Policy 40-5

The Board considered a request from Mr. Branigan to modify Policy 40-5 to allow for pharmacists to conduct remote order entry / review at a location other than a registered prescription drug outlet even at times when a pharmacist is not is not on the premises of the hospital prescription drug outlet or hospital other outlet.

After due consideration of available information, the Board voted to deny the request.

EXECUTIVE SESSION

Board President E. Katherine Edelblut moved that the Board enter into executive session as authorized by CRS 24-6-402 subsection (3)(a) roman (IIII) to discuss matters which are required by law to be kept confidential. Specifically, the provisions of law requiring these matters to be kept confidential are:

CRS 24-4-402 subsection (3)(a) romans (II) and (III), and section 13-90-107(b), which protect as confidential communications with counsel that are matters of pending or imminent litigation, or are otherwise subject to the attorney-client privilege, and CRS 25-1-1201 et sequitor, which protects the confidentiality of information pertaining to individual medical records.

The motion was unanimous.

Case Status Reports

The Board read and discussed the December 28, 2007 case status report from Mr. Acker.

The Board read and discussed the January 17, 2008 case status report from Ms. Kaye.

The Board discussed all items referred to it earlier in the meeting as well as matters confidential by law.

OPEN SESSION

2008-1418

After due consideration of the available information, the Board dismissed the compliant.

2008-1336

After due consideration of the available information, the Board dismissed the compliant.

2008-1337

After due consideration of the available information, the Board dismissed the compliant.

The Board approved admission to the REC of applicants PR-05-151 and PR-05-152.

Option Care of Denver, PDO 178

2008-1390

After due consideration, the Board rescinded the referral of this case for discipline, and dismissed the case.

Ormond L. Morford, RPh 17040 (lapsed 10/31/07)

After due consideration, the Board initiated a complaint against Mr. Morford for failing to comply with terms of his REC contract.

Rodney's Clinic Pharmacy, PDO 5-6

2008-0496

Upon receipt of a complete Transfer of Ownership application for Rodney's Clinic Pharmacy, the Board directed the rescinding of the referral of this case for discipline, and directed dismissal of the case.

ADJOURNMENT

The Board adjourned at 5:07 p.m.

Approved by E. Katherine Edelblut, RPh, President Date: March 20, 2008

Attestation:

Pursuant to § 24-6-402(2)(d.5)(I)(B), C.R.S., as Board President, I attest that the executive session of the Colorado Board of Pharmacy meeting held on January 17, 2008, was confided to the topics authorized for discussion pursuant to 24-6-402(3)(a)(II), 24-6-402(3)(a)(III), C.R.S.

Approved by E. Katherine Edelblut, RPh, President Date: March 20, 2008

Pursuant to § 24-6-402(2)(d.5)(I)(B), C.R.S., as counsel for the Board, I attest that it is my opinion that all matters discussed during the executive session of the Colorado Board of Pharmacy meeting held on January 17, 2008, constituted attorney-client communications and the contents of attorney-client discussions are not reflected within these minutes.

Approved by Jo Kaye, Assistant Attorney General Date: March 20, 2008